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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/057,198	10/26/2001	Peter M. Lloyd	509032001600	1707

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EXAMINER	
MENDOZA, MICHAEL G	

ART UNIT	PAPER NUMBER
3731	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/057,198	LLOYD ET AL.	
	Examiner	Art Unit	
	Michael G. Mendoza	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13,16-22,29-34,43,45 and 81-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13,16-22,29-34,43,45 and 81-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/10/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-3, 6, 8-13, 17, and 80 are rejected under 35 U.S.C. 102(e) as being anticipated by Rabinowitz et al. 6783753.

3. Rabinowitz et al teaches a method for delivering a physiologically active compound to a patient comprising the steps of: coating on to a substrate a physiologically active compound that when heated is the absence of a gas flow detectably decomposes; placing the substrate in an airway, wherein the airway has a cross-section area such that for volumetric gas flow through the airway of 10 – 120 liters per minute, gas speed over the compound is sufficient to decrease the decomposition of the compound upon heating; establishing a gas flow through the airway; heating the substrate, thereby heating the compound to form a vapor; allowing the vapor to mix into the gas flow, thereby cooling the vapor; allow the cooled vapor to condense to form an aerosol, wherein the aerosol has a lower fraction of decomposition than when the compound is vaporized in the absence of gas flow; and administering the resulting aerosol to a patient (col. 3, lines 44-57); wherein the gas is air; wherein the air is at

ambient temperature; wherein the cooled vapor mixed into air to form an aerosol is further mixed into an additional air stream to further cool; wherein the establishing a gas flow through the airway is caused by inhalation through the device by the patient; wherein the establish a gas flow through the airway is caused by differences in pressure; and wherein the aerosol is administered via inhalation through a mouthpiece 110; wherein the substrate is resistively heated with electrical energy (col. 10, lines 36-43).

4. As to claim 6, Rabinowitz et al. teach the use of the same or similar physiologyically active compounds. Those compounds would inherently have the same physical and chemical properties. Therefore the compounds as taught by Rabinowitz et al. would inherently detectably decompose when heated in the absence of gas flow to a temperature that substantially vaporizes the compound over a 2 second time period.

5. As to claim 12, Rabionwitz et al. teaches the method of claim 1 including the claimed compound limitations (col. 1, line 38 – col. 5, line 45).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 4, 5, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabinowitz et al.

8. As to claim 4, Rabinowitz et al. fails to specifically teach wherein the coating thickness is less than 10 μm. Rabinowitz does however teach coating a substrate with a compound. The Applicant has not disclosed that claimed thickness of the coating provides an advantage, is used for a particular purpose, or solves a stated problem. It would have been obvious to one having ordinary skill in the ar at the time the invention was made to use the claimed thickness, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routing skill in the art. *In re Aller,* 105 USPQ 233.

9. As to claim 5, Rabinowitz et al. teaches the method of claim 4, wherein the aerosol has a mass median aerodynamic diameter of between 1 – 3 μm (col. 3, lines 30-39).

10. As to claims 16 and 18, Rabinowitz et al. discloses wherein the compound is heated with resistive heaters. Rabinowitz et al. does not disclose expressively wherein the compound is heated with photon energy or by inductive means.

11. At the time the invention was made, it would have been an obvious matter to a person of ordinary skill in the art to use photon or inductive means for heating because the Applicant has not disclosed that photon or inductive means for heating provides an advantage, is used for a particular purpose, or solves a stated problem. One or ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with resistive heaters because the heaters are mechanical expedients of each other. Furthermore, it is well known in the art of heaters to use inductive heating as an alternative means for heating a substance to be vaporized as

evidenced by U.S. Patents 6923179, 6766220, 6701922, and 6681998. Therefore it would have been obvious for one having ordinary skill in the art to use inductive heating as a known alternative to resistive heating.

12. Claims 7, 19-22, 29-33, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabinowitz et al. in view of Brooks et al. 4947874.

13. As to claims 7, 19-22, 30, 32, and 43, Rabinowitz et al. teaches the method of the above 102(b) rejections. It should be noted that Rabinowitz et al. fails to specifically teach wherein the heating of the compound to form a vapor occurs over a period of 2 seconds or less. However, it is well known in the art of vaporizing heaters to vaporized a compound rapidly so that the aerosol can be inhaled during the time period of a users inhalation. In other words if the compound is not heated rapidly the compound will not be inhaled. Furthermore, Brooks et al. teaches a device with a common compound being vaporized within the claimed range for producing an aerosol. Therefore, it would have been obvious to one having ordinary skill in the art to use the claimed range of forming a vapor over a period of 2 seconds or less to provide immediate aersolization and prevent degradation of the compound from excessive heat (col. 5, lines 27-37 and col. 10, lines 13-25).

14. As to claims 29 and 31, Rabinowitz/Brooks. discloses wherein the compound is heated with resistive heaters. Rabinowitz/Brooks does not disclose expressively wherein the compound is heated with photon energy or by inductive means.

15. At the time the invention was made, it would have been an obvious matter to a person of ordinary skill in the art to use photon or inductive means for heating because

the Applicant has not disclosed that photon or inductive means for heating provides an advantage, is used for a particular purpose, or solves a stated problem. One or ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with resistive heaters because the heaters are mechanical expedients of each other. Furthermore, it is well known in the art of heaters to use inductive heating as an alternative means for heating a substance to be vaporized as evidenced by U.S. Patents 6923179, 6766220, 6701922, and 6681998. Therefore it would have been obvious to one having ordinary skill in the art to use inductive heating as a known alternative to resistive heating.

16. As to claim 33, Rabinowitz et al. teaches wherein the substrate is stainless steel foil (col. 10, lines 16-25).

17. As to claim 34, Rabinowitz et al. fails to specifically teach wherein the coating thickness is less than 10 μm. Rabinowitz does however teach coating a substrate with a compound. The Applicant has not disclosed that claimed thickness of the coating provides an advantage, is used for a particular purpose, or solves a stated problem. It would have been obvious to one having ordinary skill in the ar at the time the invention was made to use the claimed thickness, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routing skill in the art. *In re Aller,* 105 USPQ 233.

18. Claims 81 and 82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabinowitz et al. in view of Shanbrom 3949743.

19. Rabinowitz et al. teaches the method of claim 80. Rabinowitz et al. fails to teach wherein the aerosol is administered to the eye or to the skin.

20. Shanbrom teaches a method wherein an aerosol is administered to the eye or the skin for treatment of disorders. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the method of administering aerosol to the eye or to the skin for treatment of disorders (col. 3, lines 16-19).

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MM

GLENN K. DAWSON
PRIMARY EXAMINER